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DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

December 10, 2004

WARNING LETTER NYK 2005-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Holly Applegate
Ms. June Hughes
Mr. William Hughes
Jean's Greens
1545 Columbia Turnpike
Schodack, New York 12033

Dear Ms. Applegate, Ms. Hughes, and Mr. Hughes:

This letter concerns products manufactured and/or distributed by your firm, including Anti-X, Herbal Ear Drops, Cold Care Caps, Super Wound Wash, and Immune Booster Caps. FDA has reviewed the labeling for these products and has determined that they violate the Federal Food, Drug and Cosmetic Act (the Act). You can find the Act and FDA's regulations through links on FDA's Internet web site at http://www.fda.gov.

Product labeling, including your firm's Internet web site at http://www.jeansgreens.com, 2004 product catalog, product information sheets, and other information supplied with the products, shows that these products are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Act (21 U.S.C. § 321(g)(1)). The therapeutic claims in your products' labeling establish that the products are drugs because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (*see* 21 U.S.C. § 321(g)(1)(B)). For example, the labeling for your products includes the following claims:

- Anti-X: (website) "[A] special formula for patients who suffer skin burns from radiation therapy."
- Herbal Ear Drops: (website) "Inhibits or destroys bacteria or fungus present in the ear canal ...."
- Cold Care Caps: (website) "Our whole community is using this at the first onset of cold symptoms."
- Super Wound Wash:
    - Product label: "[U]sed for their antiseptic, antibiotic, pain-relieving & skin healing properties. Specific for hard to heal wounds and sores."
    - Website: "[T]raditionally used for antiseptic, antibiotic, pain-relieving & skin healing."
- Immune Booster Caps: (product information sheet) "[U]sefulness as a part of treatment programs for cancer, hypertension, hyperlipidemia, diabetes, various liver diseases, allergies, and chronic bronchitis.... [F]or patients dealing with chronic fatigue, cancer, AIDS .... [H]as cholesterol lowering, anti-tumor, anti-viral ... actions."

These claims cause your product to be drugs as defined in section 201(g)(1)(B) of the Act. Because these products are not generally recognized as safe and effective for their intended uses, they are also new drugs as defined in section 201(p) of the Act (21 U.S.C. § 321(p)). Under section 505(a) of the Act (21 U.S.C. § 355(a)), a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

Furthermore, the conditions for which Anti-X and Herbal Ear Drops are offered are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use these drugs safely for their intended purposes. Thus, the labeling for these products fails to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(1) of the Act (21 U.S.C. § 352(f)(1)).

Finally, your Cold Care Caps and Immune Booster Caps are labeled as dietary supplements; however, as explained above, their labeling also contains claims that cause the products to be drugs. Even if the labeling for these products did not contain such claims, the products would nevertheless violate other provisions of the Act as dietary supplements. For example, as dietary supplements, these products are misbranded under section 403(q)(5)(F) of the Act (21 U.S.C. § 343(q)(5)(F)) because they fail to bear a "Supplement Facts" panel, as prescribed under 21 CFR 101.36.

The above violations are not intended to be an all-inclusive list of deficiencies of your products. It is your responsibility to ensure that all products manufactured or distributed by your firm comply with the requirements of the Act and applicable regulations.

You should take prompt action to correct these violations, and any other violations existing at your firm. Failure to promptly correct these violations may result in regulatory action without further notice. Such action may include, but is not limited to, seizure of illegal products and/or an injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 days of the specific steps you have taken, or intend to take, to correct these violations. Your response should be directed to James M. Kewley, Compliance Officer, at the above address.

If you have any questions, you may contact Mr. Kewley at the above address, or by telephone at (716) 541-0328.

Sincerely,

Jerome G. Woyshner
District Director